

**Athersys**

l n c.

3201 CARNEGIE • CLEVELAND, OH 44115
(216) 431-9900 • (216) 361-9495 (F)

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Examiner Ram Shukla	Anne Brown
COMPANY:	DATE:
U.S. Patent and Trademark Office	MAY 16, 2003
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
703.746.3103	5
PHONE NUMBER:	SENDER'S PHONE NUMBER:
703.305.1677	216.426.3586
RE:	SENDER'S FAX NUMBER:
U.S. Serial No.: 09/484,331	216.361.9495

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

CONFIDENTIALITY NOTICE: THIS MESSAGE IS INTENDED FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR THE DELIVERY OF THIS MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS INFORMATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS MESSAGE IN ERROR, PLEASE NOTIFY ATHERSYS, INC. IMMEDIATELY AT (216) 431-9900, AND RETURN THE ORIGINAL MESSAGE TO 3201 CARNEGIE AVENUE, CLEVELAND, OH 44115, VIA THE U.S. POSTAL SERVICE. THANK YOU.

NOTES/COMMENTS:

PLEASE DELIVER TO EXAMINER SHUKLA.**THANK YOU.**

ATHERSYS, INC.
3201 CARNEGIE AVE, CLEVELAND, OH 44115

PTOL-413A (05-03)
Approved for use through xx/xx/xxxx. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No. 09/484,331 First Named Applicant: John J. Harrington
 Examiner: Ram Shukla Art Unit: 1632 Status of Application: After Final

Tentative Participants:

(1) Anne Brown (2) Ram Shukla
 (3) Youssef Bennani (4) Deborah Reynolds

Proposed Date of Interview: 6/3/03 Proposed Time: 10 (AM/PM)

Type of Interview Requested:

(1) Telephonic (2) Personal (3) Video Conference

Exhibit To Be Shown or Demonstrated: YES NO

If yes, provide brief description: 1.132 Declaration from Response dated 4/25/02

Appendix A from Response dated 4/25/02 and drawing

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Written description</u>	<u>62-68</u>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) <u>enablement</u>	<u>62-68</u>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) <u>112-2</u>	<u>62-63</u>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) <u>102</u>	<u>62-66</u>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continuation Sheet Attached

Brief Description of Arguments to be Presented:

Please see attached.

An interview was conducted on the above-identified application on _____.

NOTE:

This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Anne Brown
 (Applicant/Applicant's Representative Signature)

 (Examiner/SPE Signature)

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Brief Description of Arguments For Issues (1)-(4)

(1) For a claim limited to merely screening compounds for their effect on gene expression, adequate written description does not require a description of the test compounds. This is because there are no constraints on the test compounds.

(2)(a) The method is not directed to screening a drug. It is directed to screening test compounds;

(2)(b) Steps (c) and (d) are readily envisaged by the disclosure of using the RAGE cells for "drug discovery";

(2)(c) Examiner needs to clarify the basis for rejection in the paragraph spanning pages 5-6. When one tests the compound, the compound is tested on a cell that has been screened for activation of a desired gene or phenotype. The exact mechanism of activation is not relevant to the method since the screen is for only the effect of the compound on the end result (i.e., the desired phenotype or the desired gene expression).

(3) The steps asserted to be essential (and omitted) are not, in fact, essential to the claimed screening process, or are not omitted. Comparing the cell with the activated gene to the parent cell without the activated gene is inherent in screening; you are screening for a cell that expresses a gene at a higher level than the non-transfected parent. Also, there is no need to test the compound against a cell where the gene is not activated. What would be the purpose? Applicants cannot find a purpose.

Brief Description of Arguments to be Presented
Appln. No.: 09/484,331
Date: May 16, 2003
Page 2 of 2

(4) The Examiner asserts that Trueheart anticipates claim 62. To anticipate the reference must disclose a method with every element of the claimed method. The reference discloses the following. A cell that expresses a receptor protein is incubated with a test compound. The test compound activates the receptor protein. The receptor protein activates a signal transduction pathway. The signal transduction pathway activates expression of the BAR-1 gene, an endogenous gene with a heterologous promoter modified to be sensitive to the signal transduction pathway.

The claimed method differs for two reasons. First, the claim recites that the screening is for a compound that interacts with the gene product of an activated endogenous gene. In the method of Trueheart, the compound interacts with a receptor. The receptor is not a product of an endogenous activated gene. The endogenous activated gene is BAR-1. But the screening methods of Trueheart do not encompass screening for compounds that interact with BAR-1. Therefore the reference does not anticipate claim 62 for this reason alone.

Second, with the Trueheart method it is exposure to the compound itself that causes activation. The compound activates the receptor; the receptor activates the signal pathway; the signal pathway activates the BAR-1. In the claimed method, the endogenous gene is activated before the compound is ever introduced. Therefore the reference does not anticipate claim 62 for this reason alone.

Therefore the claim can be distinguished by either one or both of these differences.

